§ 1.705

§1.84, and a sequence listing in compliance with §1.821 through §1.825 (if applicable) for purposes of this paragraph on the filing date of the latest reply (if any) correcting the papers, drawings, or sequence listing that is prior to the date of mailing of either an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151, whichever occurs first.

[65 FR 56393, Sept. 18, 2000, as amended at 69 FR 21711, Apr. 22, 2004; 69 FR 50002, Aug. 12, 2004; 72 FR 46843, Aug. 21, 2007; 74 FR 52691, Oct. 14, 2009; 76 FR 74702, Dec. 1, 2011; 77 FR 46628, Aug. 6, 2012; 77 FR 49360, Aug. 16, 2012; 78 FR 19420, Apr. 1, 2013; 78 FR 62408, Oct. 21, 20131

§1.705 Patent term adjustment determination.

- (a) The patent will include notification of any patent term adjustment under 35 U.S.C. 154(b).
- (b) Any request for reconsideration of the patent term adjustment indicated on the patent must be by way of an application for patent term adjustment filed no later than two months from the date the patent was granted. This two-month time period may be extended under the provisions of \$1.136(a). An application for patent term adjustment under this section must be accompanied by:
 - (1) The fee set forth in §1.18(e); and
- (2) A statement of the facts involved, specifying:
- (i) The correct patent term adjustment and the basis or bases under §1.702 for the adjustment;
- (ii) The relevant dates as specified in §§1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in §1.703(f) to which the patent is entitled;
- (iii) Whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
- (iv)(A) Any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in §1.704; or
- (B) That there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing

or examination of such application as set forth in §1.704.

- (c) Any request for reinstatement of all or part of the period of adjustment reduced pursuant to §1.704(b) for failing to reply to a rejection, objection, argument, or other request within three months of the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request must be filed prior to the issuance of the patent. This time period is not extendable. Any request for reinstatement of all or part of the period of adjustment reduced pursuant to §1.704(b) under this paragraph must also be accompanied by:
 - (1) The fee set forth in §1.18(f); and (2) A showing to the satisfaction of
- (2) A showing to the satisfaction of the Director that, in spite of all due care, the applicant was unable to reply to the rejection, objection, argument, or other request within three months of the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request. The Office shall not grant any request for reinstatement for more than three additional months for each reply beyond three months from the date of mailing of the Office communication notifying the applicant of the rejection, objection, argument, or other request.
- (d) No submission or petition on behalf of a third party concerning patent term adjustment under 35 U.S.C. 154(b) will be considered by the Office. Any such submission or petition will be returned to the third party, or otherwise disposed of, at the convenience of the Office.

 $[65\ {\rm FR}\ 56394,\ {\rm Sept.}\ 18,\ 2000,\ {\rm as}\ {\rm amended}\ {\rm at}\ 69\ {\rm FR}\ 21711,\ {\rm Apr.}\ 22,\ 2004;\ 78\ {\rm FR}\ 19420,\ {\rm Apr.}\ 1,\ 2013]$

EXTENSION OF PATENT TERM DUE TO REGULATORY REVIEW

§ 1.710 Patents subject to extension of the patent term.

(a) A patent is eligible for extension of the patent term if the patent claims a product as defined in paragraph (b) of this section, either alone or in combination with other ingredients that read on a composition that received permission for commercial marketing or use, or a method of using such a